FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

Center for Tobacco Products
9200 Corporate Blvd.
Rockville, MD 20850

July 21-22, 2011

These summary minutes for the July 21-22, 2011 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on ____10-28-11_____.

I certify that I attended the July 21-22, 2011 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____
Caryn Cohen, M.S.
Designated Federal Official, TPSAC

_____/s/_____
Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee
July 21-22, 2011

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on July 21-22, 2011 at the Center for Tobacco Products, 9200 Corporate Blvd., Rockville, Maryland, 20850. Prior to the meeting, committee members and invited guests were provided copies of background material from the FDA, background materials from invited Industry representatives and submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Caryn Cohen, M.S. (Designated Federal Official). There were approximately 100 persons in attendance. There were 2 speakers for the Open Public Hearing session on July 21 and 5 speakers for the Open Public Hearing session on July 21. The meeting was webcast; a link to the webcast was provided on the CTP website in the Advisory Committee section.

Agenda: On the morning of July 21, 2011, the Committee discussed changes proposed by Committee members to the TPSAC Menthol Report submitted to the agency on March 18, 2011. The Committee considered additional oral and written comments from the public. The Committee considered and deliberated on proposed changes to the report and adopted amendments that constitute the advice of the Committee.

On the afternoon of July 21, 2011 and continuing on the morning of July 22, the committee initiated discussions on the issue of the nature and impact of the use of dissolvable tobacco products on the public health. These discussions began the process for the TPSAC's required report to the Secretary of Health and Human Services regarding the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children.

Attendance:

Tobacco Products Scientific Advisory Committee (Voting):
Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H. (via Tele-conference)
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D. (via Tele-conference for the menthol topic only)
Patricia Nez Henderson, M.P.H., M.D. (Public Representative)
Jack Henningfield, Ph.D. (for the menthol topic only)

Industry Representative Members Present (Non-voting):
Luby Arnold Hamm (Tobacco Growers Representative)
Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)
John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

Ex Officio Members Present (Non-Voting):
Mirjana Djordjevic, Ph.D.
Dana M. Shelton, M.P.H.

Temporary Voting Members:
Melanie Wakefield, Ph.D. (via Tele-conference for the menthol topic only)
Robert L. Balster, Ph.D. (for the dissolvable tobacco products topic only)

Fred Pampel, Ph.D. (for the dissolvable tobacco products topic only)

Consultant (Non-Voting):
Bruce Simons-Morton, Ed.D., M.P.H.

FDA Participants (Non-Voting):
David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D. (on July 21 only)
Corinne Husten, M.D., M.P.H. (for the menthol topic only)
Sarah E. Evans, Ph.D. (for the dissolvable tobacco products topic only)

Designated Federal Official:
Caryn Cohen, M.S.

The agenda was as follows:

July 21, 2011 – morning session

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
Introduction of Committee Members	
Opening Remarks	Corinne Husten, M.D., M.P.H. Senior Medical Advisor, FDA/CTP

Committee Discussion:

Open Public Hearing:
Jim Tozzi, Center for Regulatory Effectiveness

Committee Discussion:

July 21, 2011 – afternoon session

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP
Introduction of Committee Members	
FDA presentation: Dissolvable Tobacco Products	David L. Ashley, Ph.D. Director, Office of Science, FDA/CTP
FDA presentation: process for the report	Karen Templeton-Somers, Ph.D. Office of Science, FDA/CTP
Industry presentations: Marketing and Consumer Perception	
Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals

R. J. Reynolds Tobacco Company (up to 25 minutes)	Aaron P. Williams, Ph.D. Vice President Smokeless Product Development R. J. Reynolds

Industry presentations: Abuse Liability and Health Risks

R. J. Reynolds Tobacco Company (up to 25 minutes)	Charles D. Garner, Ph.D., DABT, CIH Senior Director Regulatory Oversight R. J. Reynolds
Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals

Industry presentations: Initiation and Cessation

Star Scientific (up to 25 minutes)	Curtis Wright, M.D., M.P.H. Senior Vice President & Clinical Director Rock Creek Pharmaceuticals
R. J. Reynolds Tobacco Company* (up to 35 minutes)	Geoffrey M. Curtin, Ph.D. Principal Scientist/Director Regulatory Oversight R. J. Reynolds

*Please note: As allowed, per FDA instructions for all invited industry speakers, RJRT requested and was granted any extra 10 minutes for this portion of the meeting

Adjourn for the day

July 22, 2011

Call to Order	Jonathan Samet, M.D., M.S. Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, M.S. Designated Federal Official, FDA/CTP

Introduction of Committee Members

FDA presentation: Dissolvable Tobacco Products	Sarah E. Evans, Ph.D. Office of Science, FDA/CTP

Committee Discussion

Open Public Hearing:

Elaine Keller, The Consumer Advocates for Smoke-free Alternatives Association
Wallace Picworth, Battelle
James E. Dillard, III, Altria Client Services
Jonathan Winickoff, M.D., FAAP, American Academy of Pediatrics
Greg Connolly, Harvard School of Public Health

Committee Discussion of *Questions to the Committee and Next Steps*

Adjourn

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July 21:
The morning session was devoted to the topic of menthol and finalizing the TPSAC menthol report.

Drs. Wakefield, Hatsukami, and Clanton participated by phone. The TPSAC was asked to review and discuss proposed changes to the TPSAC menthol report from chapter authors between March 18, 2011 and March 23, 2011 and to consider additional public comments.

Questions to the Committee related to menthol

1. On March 23, FDA received proposed changes to the March 18 version of the Report, although the conclusions remained the same.

   Please state whether you have:

- Any comments on any of the proposed changes;
- Any objections to any of the proposed changes;
- Any further changes you believe need to be made to the Report at this time.

   Several committee members noted minor typographical errors, which were corrected and are reflected in the final version of the report. The voting members did not request changes to the final recommendations as reflected in the March 18 version of the report.

2. TPSAC has received public comments on the Report since the announcement of this meeting, and the posting of the Menthol Report on the FDA website.

Please comment on:

- The information the public has provided to TPSAC in writing and at today's open public hearing;
- What changes, if any, need to be made to the Report in light of the information presented.

3. In the Menthol Report, TPSAC made the following recommendation: "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." If you agree, please state what scientific data, information, or reasoning was particularly persuasive to you in coming to this recommendation. If you disagree, please explain your reasoning.

Each member of the TPSAC was asked to verbally respond to question #3: "In the Menthol Report, TPSAC made the following recommendation: 'Removal of menthol cigarettes from the marketplace would benefit public health in the United States.' If you agree, please state what scientific data, information, or reasoning was particularly persuasive to you in coming to this recommendation. If you disagree, please explain your reasoning."

The eight voting members agreed with the statement in question #3 based on the strength and consistency of the data referenced in the TPSAC report. The two ex officio members agreed with the statement and noted their opinions were their own and not representative of the agencies they represent. The three industry representatives did not agree with the statement based on what they characterized as a lack of scientific evidence.
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4. Is this Menthol Report (reflecting any and all changes made during today's meeting) your report and recommendation to FDA on the public health impact of menthol in cigarettes? (voting question)

A vote was taken on the final question to the Committee regarding menthol, "Is this Menthol Report (reflecting any and all changes made during today's meeting) your report and recommendation to FDA on the public health impact of menthol in cigarettes?" The results of the vote were:

- ***Yes = 8***
- ***No = 0***
- ***Abstain = 0***

The morning session was adjourned.

At approximately 1:00 the Committee reconvened to address a new topic: the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children.

Dr. David Ashley presented the charge to the Committee, "… to review and provide recommendations to FDA regarding the nature and the impact of the use of dissolvable tobacco products on the public health, including such use among children."

Companies that FDA had reason to believe were marketing or test marketing, dissolvable tobacco products were invited to present information on their products on July 21. The companies that chose to participate – Star Scientific and R.J. Reynolds - were asked to provide three separate presentations (Altria declined the invitation) based on industry data and peer reviewed literature regarding:

1) Marketing and Consumer Perception:

- *Description of dissolvable tobacco product(s) that your company has marketed or plans to market*
- *Marketing and segmentation strategies for dissolvable tobacco products*
- *Description of how the products are designed, manufactured, and marketed to reach your target market*
- *Perception and use of dissolvable tobacco products by children and adolescents, and, even in the absence of test data, any properties which might make these products more or less attractive to children and youth*

2) Abuse Liability and Health Risks:

- *Abuse liability of dissolvable tobacco products including: product design, quantity and form of nicotine, pharmacokinetics of nicotine, potential impact on non-targeted populations. Also discuss efforts to limit or reduce abuse liability*
- *Discuss the safety profile of dissolvable tobacco products, including available information on both local and systemic adverse health effects specific to dissolvable products.*
- *Risks associated with accidental ingestion of dissolvable tobacco products by children*

3) Initiation and Cessation:

- *Whether dissolvable tobacco products might be used as starter products for non-users and how composition and design features impact use by non-tobacco product users*
- *Likelihood that users of tobacco products will completely switch to dissolvable tobacco products, as opposed to a pattern of dual use*
- *Likelihood of dissolvable tobacco products users quitting tobacco consumption in comparison to users of other tobacco products*

The six presentations are recorded verbatim in the meeting transcript and the accompanying slides can be viewed at:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm265295.htm.

The meeting adjourned at 5:15 p.m.

July 22:

Dr. Sarah Evans presented information on FDA's current and planned research activities and presented the **Questions to the Committee**:

1) Discuss the possible public health impact relating to:
   a. marketing of dissolvable tobacco products
   b. perception and use of dissolvable tobacco products by children and adults
   c. abuse liability of dissolvable tobacco products
   d. health risks of dissolvable tobacco products
   e. risk of accidental ingestion of dissolvable tobacco products
   f. features of dissolvable tobacco products that may contribute to tobacco initiation
   g. features of dissolvable tobacco products that may lead tobacco users to singular- or dual-use of dissolvable tobacco products instead of quitting

2) What additional topics, if any, would you like FDA to ask the tobacco industry to present on at the next TPSAC meeting?

3) Are you aware of any available information or research that you would like FDA to request to be presented to the TPSAC to help inform the report and recommendations on dissolvable tobacco products?

Dr. Samet reviewed some of the issues the committee would need to address in order to fulfill its charge:

- *Public health impact of the availability of dissolvables– allowing for the possibility of adverse as well as beneficial consequences.*
- *Finding the line between looking at harm reduction (which is not the TPSAC's charge in the review of dissolvables) and the health impact of dissolvables (which is part of the TPSAC's current charge).*
- *Discerning, given the paucity of data on dissolvables, which data from the realm of smokeless tobacco might be used to evaluate the issue of dissolvables.*

Committee members suggested getting more data regarding the Swedish experience, possibly using these data to extrapolate the potential U.S. experience with dissolvables. TPSAC members pointed out, however, that U.S. snus and Swedish snus are very different products (the products deliver nicotine differently, the dosing is different, they are/were marketed differently, and the "Swedish experience" is rooted within a specific cultural context).

The TPSAC identified additional issues on which they requested more information:

- *Initiation - are dissolvables more appealing to youth, would youths who initiate with dissolvables have started smoking cigarettes otherwise (an expert may need to be brought in to present on this topic)?*
- *Disease risk - particularly cardiovascular disease. There are data on the relationship between snus and cardiovascular disease; can these be used to explore the impact of dissolvables?*
- *Cessation-do dissolvables interfere with quit attempts or intent by supplying an alternative means of maintaining nicotine addiction in non-smoking environments?*
- *Packaging - what requirements if any should/can the TPSAC recommend? What are packaging requirements for other toxic substances?*
- *Marketing - what are FDA's current guidelines for marketing dissolvables and how are they currently marketed by industry?*

There were five open public hearing speakers. Their slides can be viewed at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm265295.htm and their verbatim presentations can be found in the transcript of this meeting, also posted on the web at,

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm237359.htm.

In order to evaluate health risks, the committee requested:

- *A complete list of constituents.*
- *Information about stability and generation of nitrosamines over time and in various storage conditions.*
- *Dose from time to time and batch to batch.*
- *Data on metal concentrations.*
- *Information about manufacturing procedures*
- *The variability among content/constituents/dose.*
- *Data on use during pregnancy (heavy metals and trans-placental exposure to cadmium).*

FDA plans to provide data to TPSAC as it becomes available. The committee suggested several additional resources:

- *IARC Monograph 89.*
- *Studies that evaluate the levels of heavy metals in conventional smokeless products (Dr. Lauterbach will provide).*
- *FDA standards for F-1 and F-2 packaging.*
- *2008 World Health Organization report.*
- *NSDUH data regarding use among youth and single/dual-use (Dr. Connolly referred to this in his OPH presentation).*

Generally, the TPSAC expressed the need to develop a working definition dissolvable tobacco products and determine how they fit within the broader category of smokeless tobacco.

The TPSAC requested for the next meeting:

- *A presentation on the "Swedish experience."*
- *Overview of the marketing of snus in the U.S. as an example that may be predictive of the potential impact of marketing dissolvables.*
- *More information on the docket submission from the Virginia Foundation for Healthy Youth including the methodology used to obtain their data.*
- *A presentation of Tom Eissenberg's research.*
- *More information on constituents: ingredients, doses, heavy metals, other metals (obtained from industry and/or independent study).*
- *Names of people/institutions involved in research on dissolvables.*
- *Plans for FDA collaborations with CDC related to poisoning and health effects.*
- *Industry presentations on:*
    - *Test marketing results*
    - *The population model using snus data (from Geoffrey Curtin's presentation)*

Dr. Samet encouraged the Committee members to think about developing a working definition prior to the next meeting.

The meeting adjourned at approximately 11:30 a.m.

Please see the *verbatim* transcript for details of the discussion.